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Govari

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(54) **CATHETER WITH HELICAL ELECTRODE**

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CPC ***A61B 18/1492*** (2013.01); *A61B 17/320068* (2013.01); *A61B 18/1815* (2013.01); *A61B 2018/00011* (2013.01); *A61B 2018/1407* (2013.01); *A61B 2018/1435* (2013.01); *A61B 2018/1861* (2013.01); *A61B 2218/002* (2013.01)

(58) **Field of Classification Search**

CPC A61B 18/1492; A61B 2018/00011; A61B 2018/00065; A61B 2018/00577; A61B 2018/1435

USPC 606/32, 41, 49; 29/874, 876, 877, 884, 29/837

See application file for complete search history.

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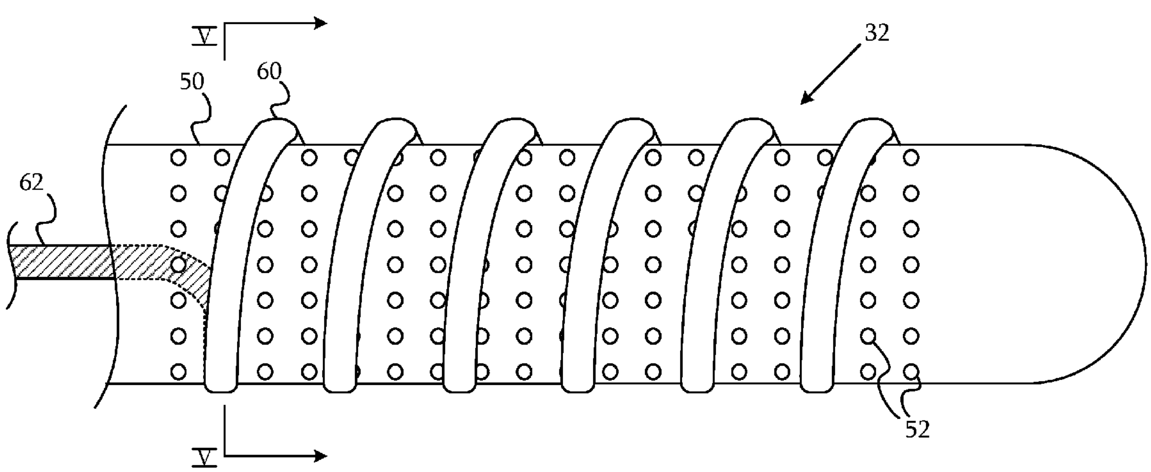
(57) **ABSTRACT**

An invasive probe includes an insertion tube containing a lumen for providing an irrigation fluid and comprising a distal portion having a plurality of perforations therethrough providing fluid communication between the lumen and an outer surface of the insertion tube. At least one helical electrode is fitted over the distal portion of the insertion tube.

10 Claims, 4 Drawing Sheets



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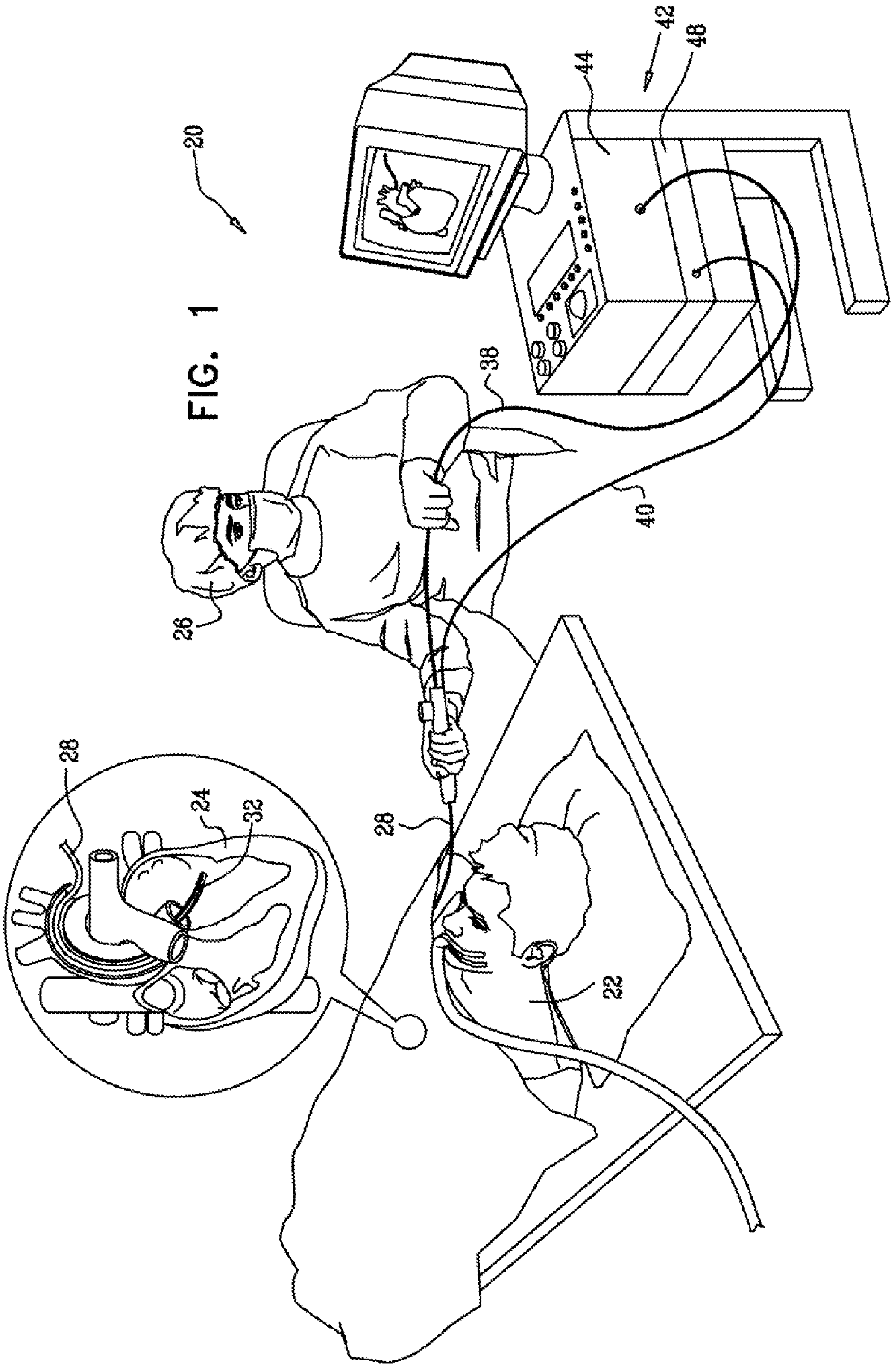

FIG. 1

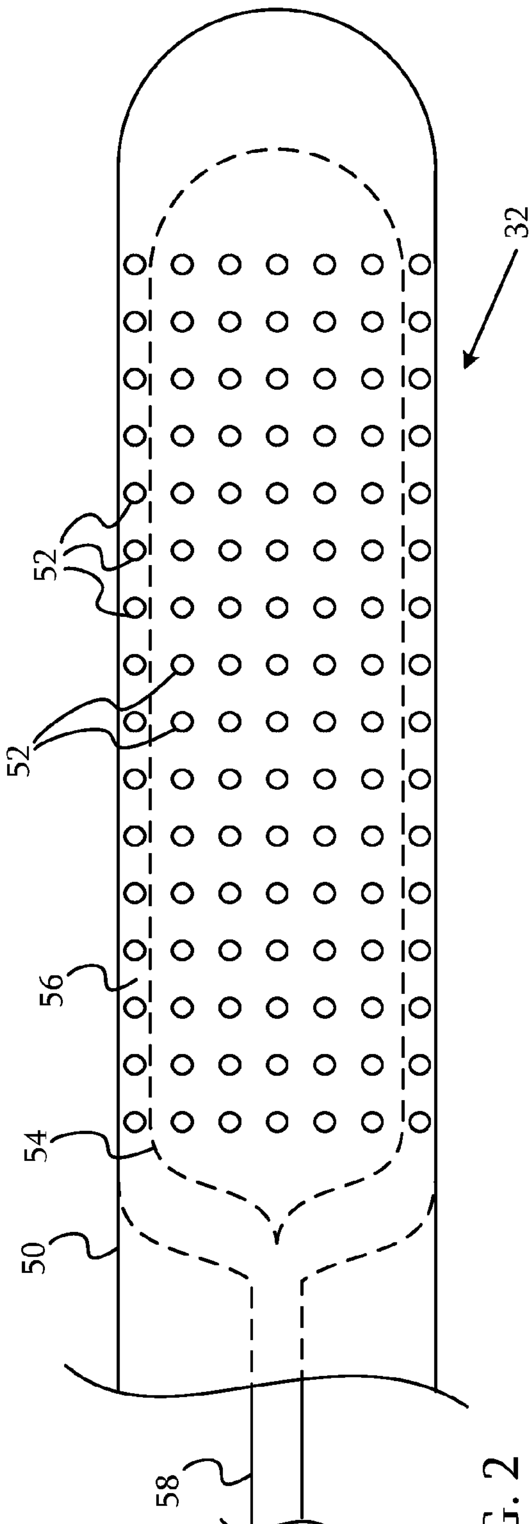

FIG. 2

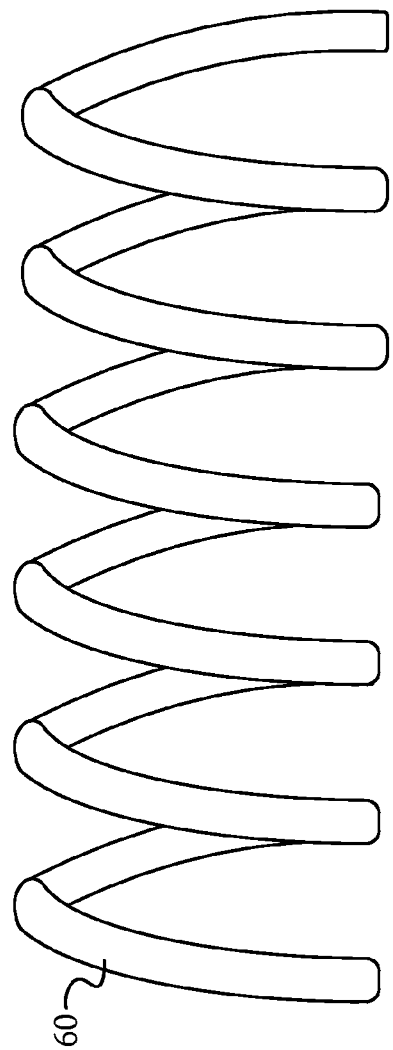

FIG. 3

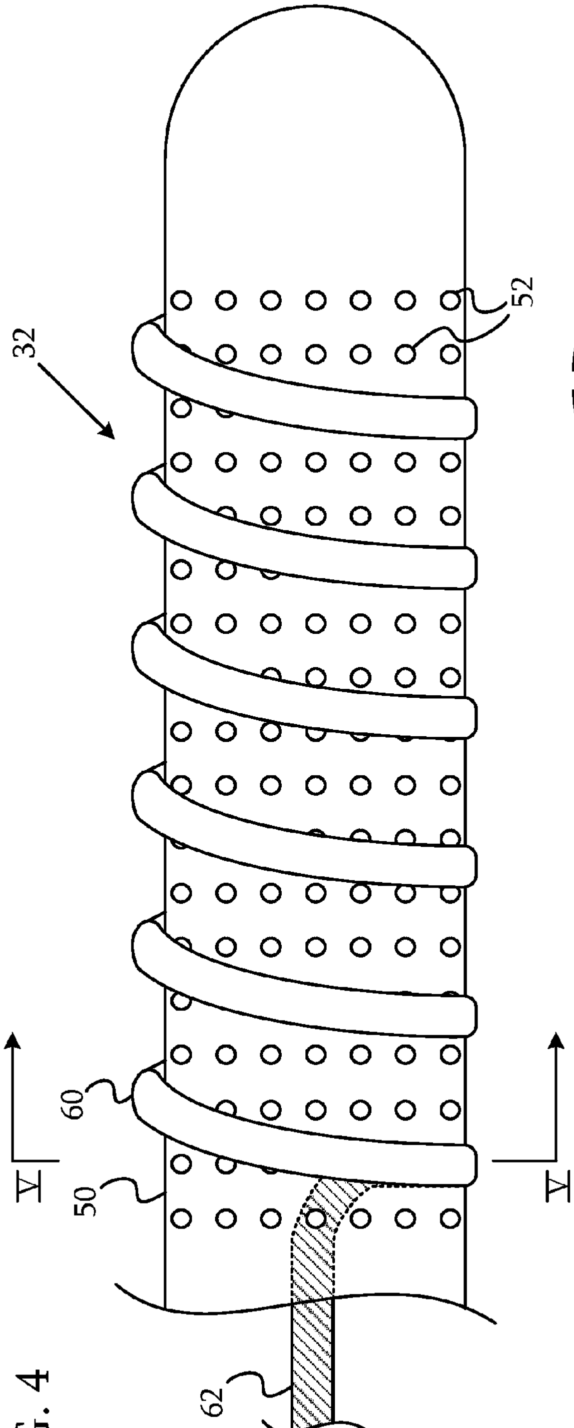

FIG. 4

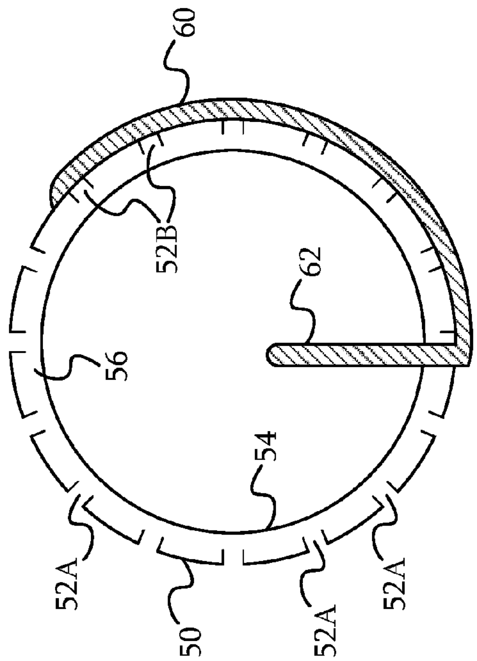

FIG. 5

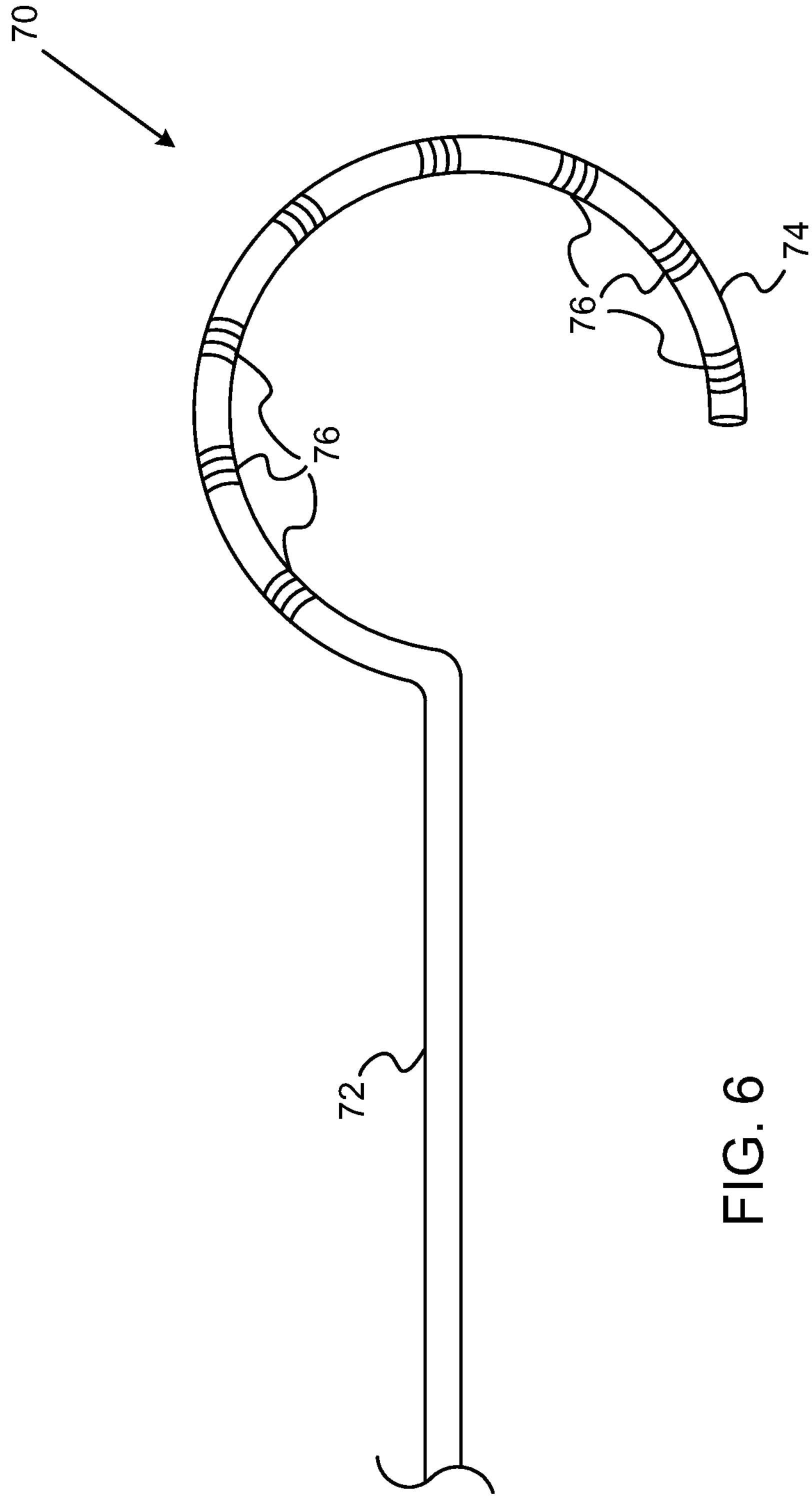

FIG. 6

CATHETER WITH HELICAL ELECTRODE

This application is a divisional of U.S. application Ser. No. 12/639,096 filed Dec. 16, 2009, the complete disclosure of which is hereby incorporated herein by reference for all purposes.

FIELD OF THE INVENTION

The present invention relates generally to medical devices, and specifically to cooling of tissue contacted by an invasive probe within the body.

BACKGROUND OF THE INVENTION

In some medical procedures, energy is imparted to body tissue locally, in a concentrated dose, and it is desirable to cool the treatment area in order to reduce collateral tissue damage.

For example, cardiac ablation therapy is used to treat arrhythmias by heating tissue with radio-frequency (RF) electrical energy to create non-conducting lesions in the myocardium. It has been found that cooling the area of the ablation site reduces tissue charring and thrombus formation. For this purpose, Biosense Webster Inc. (Diamond Bar, Calif.) offers the ThermoCool® irrigated-tip catheter as part of its integrated ablation system. The metal catheter tip, which is energized with RF current to ablate the tissue, has a number of peripheral holes, distributed circumferentially around the tip, for irrigation of the treatment site. A pump coupled to the catheter delivers saline solution to the catheter tip, and the solution flows out through the holes during the procedure in order to cool the catheter tip and the tissue.

SUMMARY

Embodiments of the present invention that are described hereinbelow provide irrigated probes for invasive medical procedures, such as irrigated catheters for use in RF ablation, as well as efficient methods for manufacturing such probes.

There is therefore provided, in accordance with an embodiment of the present invention, an invasive probe, including an insertion tube containing a lumen for providing an irrigation fluid and including a distal portion having a plurality of perforations therethrough providing fluid communication between the lumen and an outer surface of the insertion tube. At least one helical electrode is fitted over the distal portion of the insertion tube.

Typically, the probe includes one or more wires that pass through the tube and are electrically coupled to the at least one helical electrode. Additionally or alternatively, the at least one helical electrode covers some of the perforations.

In one embodiment, the at least one helical electrode includes multiple helical electrodes, which are distributed along the distal portion.

In a disclosed embodiment, the insertion tube is configured for insertion through a blood vessel into a chamber of a heart of a subject, so as to bring the at least one helical electrode into contact with endocardial tissue in the heart.

Typically, the plurality of the perforations includes at least eight perforations, and possibly at least fifty perforations. The perforations typically have a diameter less than 0.5 mm, and possibly less than 0.2 mm. The perforations may have respective sizes that vary depending on respective longitudinal locations of the perforations.

In one embodiment, the at least one helical electrode includes a wire coil helically wound about the distal portion of the insertion tube. In another embodiment, the at least one helical electrode includes a tube cut out along a spiral pattern.

There is also provided, in accordance with an embodiment of the present invention, medical apparatus, including a probe, for insertion into a body of a subject. The probe includes an insertion tube containing a lumen and including a distal portion having a plurality of perforations therethrough providing fluid communication between the lumen and an outer surface of the insertion tube, with at least one helical electrode fitted over the distal portion of the insertion tube and configured to contact tissue in the body. An energy generator is coupled to the probe so as to supply electrical energy to the at least one helical electrode. An irrigation pump is coupled to the lumen so as to supply an irrigation fluid via the lumen and the perforations to the tissue.

In a disclosed embodiment, the energy generator is coupled to supply electrical energy to the at least one helical electrode in order to ablate the tissue. For example, the probe may be configured for insertion through a blood vessel into a heart of the subject for ablation of myocardial tissue in the heart.

There is additionally provided, in accordance with an embodiment of the present invention, a method for treatment, including inserting a probe into a body of a subject. The probe includes an insertion tube containing a lumen and including a distal portion having a plurality of perforations therethrough providing fluid communication between the lumen and an outer surface of the insertion tube, with at least one helical electrode fitted over the distal portion of the insertion tube. The at least one helical electrode is brought into contact with tissue in the body. Electrical energy is applied through the at least one helical electrode to the tissue, and an irrigation fluid is supplied via the lumen and the perforations to the tissue.

Typically, the fluid is supplied in order to cool the distal portion and the tissue.

There is further provided, in accordance with an embodiment of the present invention, a method for producing a medical device, including creating a plurality of perforations through an outer surface of a distal portion of an insertion tube containing a lumen so as to provide fluid communication between the lumen and an outer surface of the insertion tube. At least one helical electrode, including a conductive material, is slid over the distal portion of the insertion tube. The at least one helical electrode is then affixed to the outer surface of the distal portion of the insertion tube.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic, pictorial illustration of a system for cardiac ablation therapy, in accordance with an embodiment of the present invention;

FIG. **2** is a schematic side view of a perforated catheter insertion tube, in accordance with an embodiment of the present invention;

FIG. **3** is a schematic side view of a coil electrode, in accordance with an embodiment of the present invention;

FIG. **4** is a schematic side view of the distal portion of a perforated catheter onto which a coil electrode has been fitted, in accordance with an embodiment of the present invention;

FIG. **5** is a schematic, cross-sectional view of the catheter of FIG. **4**, taken along a line V-V; and

FIG. **6** is a schematic side view of a lasso catheter with coil electrodes, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

In RF electrical ablation procedures, as noted earlier, irrigating the area of the ablation site reduces tissue charring, thrombus formation, and adhesion between the ablation electrode and the tissue. Methods and devices for irrigation to date have required that the electrode itself be perforated so that irrigation fluid can pass out of the catheter through the perforations into the treatment area. A perforated electrode of this type and methods for producing the perforations are described, for example, in U.S. patent application Ser. No. 12/173,150, filed Jul. 15, 2008, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference. Creating the perforations is time-consuming and costly, however, and may weaken the electrode structure.

Embodiments of the present invention that are described hereinbelow provide a simple, inexpensive method for producing ring electrodes with irrigation. An invasive probe, such as a catheter, is produced with multiple perforations through its outer wall in the area in which a ring electrode is to be placed. The perforations communicate with a lumen inside the probe, which conveys irrigation fluid to the perforations. A conductive coil electrode, typically having the form and resilience of a helical spring, is fitted over and fixed to the probe at the desired electrode location. This coil electrode is connected to one or more wires running through the probe, which may be used, for example, to provide RF electrical energy to the coil for ablation therapy. Although the placement of the coil electrode will typically cover some of the perforations in the wall of the probe, other perforations, in the gaps between the turns of the coil, remain uncovered. During operation, these open perforations provide irrigation throughout the treatment area.

The design described above and shown in the figures that follow is easy and inexpensive to manufacture. It provides the benefits achieved by a perforated, irrigated electrode, while avoiding the difficulty and costs of actually creating the perforations in the electrode. This sort of electrode structure can be used in creating multiple ring electrodes along the length of a catheter or other structure, such as lasso.

FIG. **1** is a schematic, pictorial illustration of a system **20** for cardiac ablation therapy, in accordance with an embodiment of the present invention. An operator **26** inserts a catheter **28** through a blood vessel into a chamber of a heart **24** of a subject **22**, and manipulates the catheter so that a distal portion **32** of the catheter contacts the endocardium in an area that is to be treated. The distal portion of the catheter is perforated to enable irrigation of the treatment area, as shown and described hereinbelow. In other respects, however, system **20** resembles systems for cardiac ablation treatment that are known in the art, such as the above-mentioned Biosense Webster system, and the components of such systems may be adapted for use in system **20**.

After positioning distal portion **32** of catheter **28** at an ablation site, and ensuring that an electrode on the distal portion (as shown below) is in contact with the endocardium at the site, operator **26** actuates a radio frequency (RF) energy generator **44** in a control console **42** to supply RF energy via a cable **38** to the electrode. Meanwhile, an irrigation pump **48** supplies a cooling fluid, such as saline solution, via a tube **40** and a lumen in catheter **28** to the distal portion. Operation of the RF energy generator and the irrigation pump may be coordinated in order to give the appropriate volume of irrigation during ablation, so as to cool the electrode and the tissue without overloading the heart with irrigation fluid. A temperature sensor (not shown in the figures) in distal portion **32** may provide feedback to console **42** for use in controlling the RF energy dosage and/or irrigation volume.

FIG. **2** is a schematic side view of a portion of an insertion tube **50** of catheter **28**, in accordance with an embodiment of the present invention. The figure shows the distal portion of the insertion tube at a stage of manufacturing before assembly of an electrode onto distal portion **32**. Tube **50** typically comprises a suitable biocompatible plastic, such as polyurethane, which is typically about 2.3 mm in diameter, with a wall thickness of about 0.15 mm. These dimensions, however, are given solely by way of illustration, and larger or smaller dimensions may be used depending on application requirements.

The outer surface of the distal portion of tube **50** is penetrated by multiple perforations **52**, which are distributed over the surface of the distal tip both longitudinally (i.e., along the direction parallel to the longitudinal axis of catheter **28**) and circumferentially (along circumferences around the axis). The perforations may be formed in tube **50** by any suitable method known in the art, such as pre-molding of the perforations at the time of fabrication of the tube, or punching or drilling (by laser or mechanical means) the perforations into the tube after extrusion.

Distal portion **32** contains an interior reservoir **56**, which is fed with irrigation fluid by a lumen **58** inside tube **50**. Perforations **52** extend between reservoir **56** and the outer surface of tube **50**. In the embodiment shown in the figures, reservoir **56** has an inner surface **54**, which may be formed, for example, by a fitting a tube of smaller diameter inside tube **50**. Alternatively, the reservoir may occupy the entire interior space at the distal tip of tube **50**, which may then be closed off by a plug (not shown) proximal to the distal tip, through which lumen **58** feeds. Alternative reservoir configurations will be apparent to those skilled in the art and are considered to be within the scope of the present invention.

Typically, tube **50** has at least eight perforations, which are less than 0.5 mm in diameter, in order to distribute the irrigation over the area of distal portion both longitudinally and circumferentially without overloading the heart with the cooling fluid. The inventors have found it advantageous, however, to have at least fifty perforations in the distal portion, with diameters no greater than 0.2 mm, and possibly as small as about 0.1 mm. The sizes of the perforations may optionally be varied over the length of the distal tip to compensate for pressure variation and ensure equal flow over the entire length. For this purpose, the perforations at and near the most distal part of the tip may be made larger than the more proximal perforations, which are nearer to the fluid inlet.

FIG. **3** is a schematic side view of a coil electrode **60**, in accordance with an embodiment of the present invention. This electrode is fitted over tube **50**, as shown in the figures that follow. Electrode **60** typically comprises a resilient, biocompatible conductive material, such as gold, platinum or iridium wire, or an alloy of such metals. The coil electrode may comprise a wire, which is wound into a helical coil, as shown in the figure, resembling a coil spring. Alternatively, the coil electrode may be made from a tube, which is cut out along a spiral pattern to create a helical shape, using laser cutting, for example. The coil electrode has an inner diameter equal to or slightly smaller than the outer diameter of tube **50**, so that the coil will fit snugly over the tube.

Reference is now made to FIGS. **4** and **5**, which schematically show distal portion **32** of catheter **28**, made by fitting coil electrode **60** over tube **50**, in accordance with an embodiment of the present invention. FIG. **4** is a side view, while FIG. **5** is a cross-sectional view taken along the line marked V-V in FIG. **4**. Electrode **60** is slid to the desired location on tube **50**, and is then glued or otherwise fastened in place. One or more wires **62** inside tube **50** penetrate through the outer surface of the tube (possibly through one of perforations **52**) and are soldered or otherwise bonded to electrode **60**. Any suitable technique that is known in the art for electrical coupling to ring electrodes may similarly be used for this purpose. Wires **62** run through to the proximal end of catheter **28**, where they connect via cable **38** to RF energy generator **44** (FIG. **1**).

As can be seen in FIGS. **4** and **5**, when electrode **60** is fastened over tube **50**, it covers some of the perforations (marked **52**B in FIG. **5**). A sufficient number of the perforations (marked **52**A) remain open, however, to provide adequate irrigation of the area contacted by the electrode. This arrangement is advantageous in that it obviates the need for high positional precision in forming perforations **52** in tube **50** and in placing electrode **60** on the tube. During the ablation procedure, lumen **58** (FIG. **2**) conveys fluid from irrigation pump **48** (FIG. **1**) to reservoir **56**. The fluid exits tube **50** through perforations **52**A to the surrounding tissue while electrode **60** delivers the RF energy in order to ablate the tissue.

FIG. **6** is a schematic side view of a lasso catheter with coil electrodes **76**, in accordance with an embodiment of the present invention. The lasso catheter insertion tube is formed to define a shaft **72** with a distal portion **74** having a roughly circular lasso shape. This sort of lasso shape can be used, for example, in ablating myocardial tissue along a circular path around the ostia of the pulmonary veins in treatment of atrial fibrillation.

In order to ablate multiple locations simultaneously along the desired path, electrodes **76** are distributed around the circumference of distal portion **74**. Each electrode is slid into place, fastened, and connected electrically to wires inside catheter **70** in the manner described above. Distal portion **74** may also have perforations (not shown in this figure) for the purpose of irrigation, as in catheter **28**. Multiple coil electrodes may likewise be distributed along the length of catheters of other types, as well as on other sorts of tubular probes.

Although the embodiments described above relate specifically to catheters used in RF ablation treatment within the heart, the principles of the present invention may similarly be applied to other organs and in other types of diagnostic and therapeutic procedures, particularly procedures that involve application of energy to body tissues. For example, a device with a similar sort of irrigated tip may be used in therapies that involve microwave-based or ultrasonic tissue heating. As another example, coil electrodes of the type described above may also be used without irrigation on catheters and tubular probes of other types.

It will thus be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

What is claimed is:

1. A method for producing a medical device, comprising:
creating a plurality of perforations through an outer surface of a distal portion of an insertion tube containing a lumen and having an outer diameter, so as to provide fluid communication between the lumen and an outer surface of the insertion tube;
cutting a metal tube into a spiral pattern to form at least one helical electrode, the helical electrode having an inner diameter slightly smaller than the outer diameter of the insertion tube; and
after cutting the metal tube to form the at least one helical electrode, sliding said formed at least one helical electrode over the distal portion of the insertion tube; and
affixing the at least one helical electrode to the outer surface of the distal portion of the insertion tube.

2. The method according to claim **1**, and comprising passing one or more wires through the tube and electrically coupling the wires to the at least one helical electrode.

3. The method according to claim **1**, wherein the at least one helical electrode covers some, but not all, of the perforations.

4. The method according to claim **1**, wherein sliding the at least one helical electrode comprises positioning multiple helical electrodes along the distal portion.

5. A method for producing a medical device, comprising:
creating a plurality of perforations through an outer surface of a distal portion of an insertion tube containing a lumen so as to provide fluid communication between the lumen and an outer surface of the insertion tube;
winding a metal wire into a helical coil to form a helical electrode, the helical electrode having an inner diameter slightly smaller than the outer diameter of the insertion tube; and
after the step of winding, sliding said at least one helical electrode over the distal portion of the insertion tube; and
affixing the at least one helical electrode to the outer surface of the distal portion of the insertion tube.

6. The method according to claim **5**, and comprising passing one or more wires through the tube and electrically coupling the wires to the at least one helical electrode.

7. The method according to claim **5**, wherein the at least one helical electrode covers some, but not all, of the perforations.

8. The method according to claim **5**, wherein sliding the at least one helical electrode comprises positioning multiple helical electrodes along the distal portion.

9. The method according to claim **1** or **5**, wherein the size of the perforations are varied over the length of the distal portion to compensate for pressure variation and flow over the length of distal portion.

10. The method according to claim **1** or **5**, wherein the perforations are sized and configured to ensure near equal flow of the entire length of the distal portion.

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